

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BIOVAIL LABORATORIES, INC.,  
a corporation of Barbados,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,  
a corporation of Delaware,

Defendant.

Civil Action No. 05-cv-1085

FILED

JAN 6 - 2006

MICHAEL C. KUNZ, Clerk  
by [Signature] Dep. Clerk

**STIPULATED CONFIDENTIALITY AGREEMENT AND PROTECTIVE ORDER**

Plaintiff, Biovail Laboratories, International, SRL ("Biovail"), and defendant, Impax Laboratories, Inc. ("Impax"), by their undersigned counsel, hereby stipulate and agree, subject to the approval of the Court, to the following limitations on the use and dissemination of documents and other information obtained through discovery in the litigation entitled Biovail Laboratories, Inc. v. Impax Laboratories, Inc., United States District Court for the Eastern District of Pennsylvania, Case No. 05-CV-1085 (the "case" or "litigation").

1. It is likely that certain information, documents, formulas and things of the parties and third parties, which are otherwise discoverable under the Federal Rules of Civil Procedure, may contain or be claimed to contain trade secrets, know-how, or other confidential research, development, technical, commercial or financial information, and in the interest of permitting discovery to proceed in the case without delay occasioned by possible disputes regarding such claims of confidential information, the following Stipulated Confidentiality Agreement and Protective Order (the "Protective Order") should be entered pursuant to Rule 26(c) of the Federal Rules of Civil Procedure for the protection of the parties' confidential and trade secret

information. This Protective Order shall be binding on all counsel for the parties who are permitted access to confidential information under the terms hereof, but shall not impair the right of any party or third party to assert that confidential information is also covered by the attorney-client and/or work product privileges.

2. This Protective Order shall apply to all confidential information, documents and things subject to discovery in this action, including without limitation, testimony adduced at deposition upon oral examination, answers to interrogatories, documents or other things produced or obtained, and responses to requests for admission pursuant to the Federal Rules of Civil Procedure.

3. The term "Confidential Information" means information that is disclosed in discovery or pursuant to disclosure rules that is designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL by any party or non-party to this litigation. Such designation constitutes certification by the designating party that (i) the item of discovery so designated has been reviewed and a determination made that it is Confidential Information; (ii) disclosure of such information without restriction would be detrimental to that party in the conduct of its business and cause cognizable harm; (iii) the designating party represents that it and its counsel know what constitutes confidential information and that it and its counsel are acting in good faith when designating any material as such; and (iv) there is good cause for seeking the Court's protection.

4. Written information, documents or things, or any portion thereof, shall be designated as Confidential Information by placing on each page a stamp or notice stating:

**CONFIDENTIAL**

**or**

**HIGHLY CONFIDENTIAL**

(or comparable legend) in a manner that will not interfere with the legibility of the written information. If any Confidential Information is inadvertently produced without such stamp or notice, the producing party will provide written notice to the receiving party that the information or documents shall be treated as CONFIDENTIAL or HIGHLY CONFIDENTIAL under this Protective Order (as appropriate), and the producing party will promptly thereafter furnish the receiving party with a substitute set of documents bearing the correct stamp or notice and the receiving party will return or destroy the original set and any copies of the original set.

5. Inadvertent production of any document subject to the attorney-client privilege, the attorney work product privilege, or any other applicable privilege or immunity shall not constitute a waiver of the privilege or immunity, provided that the producing party promptly notifies the receiving party in writing of such inadvertent production after the producing party discovers such inadvertent production. If prompt notification is made and the producing party establishes the circumstances surrounding the document's inadvertent production and the grounds for an applicable privilege or immunity, such inadvertently produced document and all copies thereof shall promptly be returned to the producing party or destroyed, upon request. The receiving party shall not make any use of such document during deposition or trial, nor shall the receiving party show the document to anyone who was not already given access to it prior to the producing party's request to return or destroy. If, after conferring, the parties cannot agree as to whether a document should be protected from disclosure by a privilege or immunity, the producing party shall have ten (10) business days to file a motion with the court seeking the

return or destruction of the produced document. While such a motion is pending, the receiving party shall not make any use of such document during deposition or at trial, nor shall such document be shown by the receiving party to anyone who was not already given access to it prior to the producing party's request to return or destroy.

6. With respect to all original documents that are made available for inspection, designation by stamping as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" need not be made until copies of the materials are requested after inspection and selection by counsel. Making documents available for inspection shall not constitute a waiver of any claim of confidentiality, and all materials made available for inspection shall be treated as if designated as HIGHLY CONFIDENTIAL pursuant to this Protective Order at the time of inspection.

7. Information disclosed at any deposition may be designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL by a statement on the record or within fifteen (15) business days of the receipt of the transcript of the deposition, that the testimony, or a portion of the testimony, is confidential and subject to the provisions of this Protective Order.

8. Matter designated as HIGHLY CONFIDENTIAL may include, without limitation, financial information, customer identification, future business plans, research and development work and trade secrets. Matter shall not be designated as HIGHLY CONFIDENTIAL unless the producing party in good faith believes that revealing that matter to persons to whom CONFIDENTIAL matter may be disclosed will or may cause injury to the producing party.

9. Confidential Information shall be used only for the purposes of this litigation, shall not be used by any recipient for any commercial purpose or for (i) filing or prosecuting any patent application (of any type) or patent reissue or reexamination request; (ii) filing or

prosecuting any trademark or trade dress application or reissue; or (iii) filing any copyright application, registration or renewal. Nothing contained herein shall preclude any party from asserting any of its rights under any patent, trademark or copyright it owns or otherwise has the right to enforce, and to seek damages and/or equitable remedies for any infringements thereof.

10. As to produced matter designated CONFIDENTIAL, such information shall not be disclosed, given, shown, made available or communicated to anyone other than:

- (a) the Court and its personnel, including clerks and court reporters;
- (b) the attorneys of record and their partners, associates, paralegals, secretaries and employees, as well as outside copying, graphic or design services, computer services and court reporters performing services in conjunction with this litigation;
- (c) Biovail's or Impax's in-house counsel;
- (d) outside technical advisors and/or experts ("experts"), as are deemed necessary in the judgment of the receiving party, for performing services in this litigation, pursuant to the procedure set forth in paragraph 14 below;
- (e) the author(s) or prior recipient(s) of a document containing Confidential Information, provided it is established in the document or by agreement of the parties that the person is an author or prior recipient of the document.

11. Before the disclosure of any Confidential information to any person covered by subparagraph 10(c), such person shall be cautioned against the disclosure of said information to anyone else and shall be advised that the said information is the subject of a Court Order and such person shall acknowledge his/her agreement to abide by this Order and to be subject to the

jurisdiction of this Court by signing a declaration in the form attached as Exhibit A, a copy of which shall be provided to counsel for all parties and non-parties who have produced Confidential information under this Order. A party having a special need for disclosing the opposing party's Confidential information to the party's employee other than in-house counsel as provided in subparagraph 10 (c) may do so only pursuant to the following procedure: notice shall be made by serving an executed declaration in the form attached as Exhibit A, along with a written statement setting forth that employee's present business address, job title, supervisor, and duties and responsibilities. No Confidential Information shall be disclosed to such employee until after the expiration of ten (10) business days commencing with the service by facsimile upon counsel of said notice. If any party objects to the disclosure of confidential information to that employee within the ten (10) business day period after receiving such notice, no such disclosure shall be made to that employee without prior approval of the Court or the objecting party. Any objection shall be in writing and state with particularity the basis for the objection. Although the objecting party shall have the ultimate burden of showing why that employee should not have access to confidential information, the party seeking to disclose such information shall have the initial burden of moving the Court for permission to disclose information to such employee. Pending resolution of any such motion, no disclosure of Confidential Information shall be made to that employee.

12. As to produced or revealed matter designated as HIGHLY CONFIDENTIAL, such information shall not be disclosed, given, shown, made available or communicated to anyone other than:

- (a) the Court and its personnel, including clerks and court reporters;

- (b) the attorneys of record and their partners, associates, paralegals, secretaries and employees, as well as outside copying, graphic or design services, computer services and court reporters performing services in conjunction with this litigation;
- (c) one Biovail in-house counsel and one Impax in-house counsel, each having signed and provided to counsel for the opposing party an executed declaration in the form attached as Exhibit A and having further agreed in writing to refrain from the prosecution of patent applications for bupropion hydrochloride extended release formulations for a period of two years after the conclusion of this litigation;
- (d) outside technical advisors and/or experts ("experts"), as are deemed necessary, in the judgment of the receiving party, for performing services in this litigation, pursuant to the procedure set forth in paragraph 14 below; and
- (e) the author(s) or prior recipient(s) of a document containing Confidential Information, provided it is established in the document or by agreement of the parties that the person is an author or prior recipient of the document.

13. All individuals, except the Court and the Court's staff, to whom Confidential Information is disclosed shall, prior to such disclosure, be informed of the existence of this Protective Order, and be instructed that such matter may not be used other than in connection with this litigation.

14. Before Confidential Information or Highly Confidential Information may be disclosed to any expert as provided in subparagraphs 10(d) and 12(d), the party retaining the

expert shall provide notice of the intended disclosure. The notice shall be made by serving an executed declaration in the form attached as Exhibit A, along with a written statement setting forth that person's present residence address, business address, employer, job title and any past or present association with any party, and a curriculum vitae, including a list of publications and a list of the expert's clients in any ongoing consultations and any consultations within the last five (5) years relating to the pharmaceutical field or industry. No Confidential Information or Highly Confidential Information shall be disclosed to such expert until after the expiration of ten (10) business days commencing with the service by facsimile upon counsel of said notice. If any party objects to the disclosure of confidential information to that person within the ten (10) business day period after receiving such notice, no such disclosure shall be made to that person without prior approval of the Court or the objecting party. Any objection shall be in writing and state with particularity the basis for the objection. Although the objecting party shall have the ultimate burden of showing why that person should not have access to confidential information, the party seeking to disclose such information shall have the initial burden of moving the Court for permission to disclose information to such person. Pending resolution of any such motion, no disclosure of Confidential Information or Highly Confidential Information shall be made to that person. A non-testifying expert to whom a party has disclosed the opposing party's Confidential Information or Highly Confidential Information as provided in subparagraphs 10(d) and 12(d) may not be called to testify at deposition or trial by the opposing party without prior approval of the Court or the party.

15. Should any Confidential Information or Highly Confidential Information be disclosed, through inadvertence or otherwise, by the receiving party to any person or party not authorized under this Protective Order, then the receiving party shall (a) use its best efforts to



obtain the return of any such Confidential Information or Highly Confidential Information and to bind such persons to the terms of this Protective Order; (b) within three (3) business days of the discovery of such disclosure, inform such person of all provisions of this Protective Order; (c) within five (5) business days of the discovery of such disclosure, identify such person to the producing party; and (d) request such person to sign the Declaration attached as Exhibit A. The executed Declaration shall be served upon counsel of record for the producing party within five (5) business days of its execution by the party to whom Confidential Information or Highly Confidential Information was disclosed.

16. Counsel and all other persons to whom Confidential or Highly Confidential Information is disclosed pursuant to this Protective Order shall take reasonable and appropriate precautions to avoid loss or inadvertent disclosure of the Confidential Information.

17. If a party wishes to file Confidential Information with the Court, it shall take reasonable steps to ensure that such information is impounded, kept under seal, and unavailable to the public, in accordance with the applicable Federal Rules of Civil Procedure and the Local Rules of this Court.

18. Nothing in this Protective Order shall prohibit the use of, or reference to, any Confidential Information in court or in any deposition; provided, however, that the party using or planning to use such information shall take reasonable steps to eliminate or minimize the risk of disclosure to unauthorized persons.

19. All Confidential Information filed with the Court shall be filed in sealed envelopes or containers that contain the statement (or a similar legend):

**CONFIDENTIAL (or HIGHLY CONFIDENTIAL)**

**This envelope (or container) contains documents, materials, or other things that are impounded until further Order of the**

**Court. The contents of this envelope (or container) shall not be displayed or revealed except by Order of the Court.**

20. This Protective Order applies to the pre-trial phase of this action and any hearings or preliminary injunction proceedings held before a final trial on the merits. Prior to trial of the action, counsel for the parties shall attempt to reach agreement on the handling of Confidential Information at trial, and shall submit such agreement or proposals to the Court for consideration. If no agreement is reached, the parties, by Motion, shall submit the matter to the Court for decision.

21. Within sixty (60) days after the conclusion of this litigation, including all appeals, any Confidential Information (including copies and originals) shall, at the request of the party that designated the information confidential, be certified as destroyed or returned to the designating party.

22. Neither the termination of this lawsuit nor the termination of employment of any person with access to any Confidential Information shall relieve such person from the obligation of maintaining the confidentiality of such information.

23. Nothing contained in this Protective Order shall be construed as an admission by any party that receives documents or other materials designated CONFIDENTIAL or HIGHLY CONFIDENTIAL that such materials are, in fact, Confidential Information within the meaning of this Protective Order. A party shall not be obligated to challenge the propriety of a CONFIDENTIAL or HIGHLY CONFIDENTIAL designation at the time made, and a failure to do so shall not preclude a subsequent challenge thereto. In the event that any party to this litigation disagrees at any stage of these proceedings with the designation by the supplying party of CONFIDENTIAL or HIGHLY CONFIDENTIAL, the parties will first try to dispose of such

dispute in good faith on an informal basis. If the dispute cannot be resolved, the objecting party may seek appropriate relief from the Court, and the party seeking to challenge the designation shall have the burden of proving that the designated information is not CONFIDENTIAL or HIGHLY CONFIDENTIAL.

24. All documents and other materials designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL shall be treated by a recipient as such under the terms of this Protective Order unless and until such designation is revoked by the designating party or the Court pursuant to this paragraph.

25. Nothing contained in this Protective Order shall be construed as a waiver by any party of its right to object to any discovery request made in this action. The execution of this Protective Order shall not constitute a waiver by any party of any applicable privilege or immunity.

26. Nothing in this Protective Order shall affect the right of the designating party to disclose its own Confidential Information to any person or entity. Such disclosure shall not waive any of the protections of this Protective Order.

27. If a third party provides discovery to any party in the above-captioned litigation, such third party may adopt the terms of this Protective Order with regard to the production of Confidential Information by executing and filing with the Court a notice of election in the form attached hereto as Exhibit "B." In the event of such election, the provisions of this Protective Order shall apply to such discovery as if such discovery were being provided by a party to this litigation. Under such circumstances, the third party shall have the same rights and obligations under this Protective Order as held by the parties to this litigation.

28. The restrictions of this Protective Order shall not apply to any information which is made known to a party:

(a) on a non-confidential basis or which is made known to a party on any basis by any source, other than another party, provided that source obtained the information lawfully and under no obligation of confidentiality to a party;

(b) without any restriction as to the confidentiality at the time of disclosure and not subject to a subsequent agreement regarding the confidentiality of such document(s); or

(c) which becomes a matter of public knowledge as a result of acts or events not involving a violation of this Protective Order or any other agreement regarding confidentiality.

Nothing herein restricts a producing party's use of its own CONFIDENTIAL or HIGHLY CONFIDENTIAL documents or information.

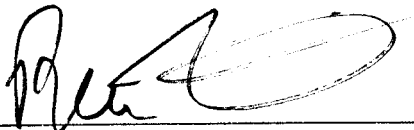
29. This Protective Order may be modified by written stipulation of the parties without further Order of the Court.

30. This Protective Order is entered without prejudice to the right of any party to apply to the Court at any time, for good cause or when convenience or necessity requires, for additional protection, modifications of the terms of this Order, or to relax or rescind the restrictions of this Order.

31. This Protective Order shall not bar attorneys from advising their clients with respect to this litigation, or generally commenting on Confidential Information, so long as such advice or comment does not disclose the Confidential Information.

Respectfully submitted,

**FOX ROTHSCHILD, LLP**

By 

Abraham C. Reich

PA I.D. #20060

James L. Griffith

PA I.D. # 05023

Robert Tintner

PA I.D. # 73865

2000 Market Street

10<sup>th</sup> Floor

Philadelphia, PA 19103

(215) 299-2000

**ATTORNEYS FOR PLAINTIFF  
BIOVAIL LABORATORIES,  
INTERNATIONAL, SRL**

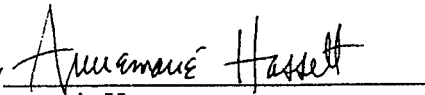
Dated: December 30, 2005

APPROVED BY THE COURT:

\_\_\_\_\_  
Anita B. Brody, U.S.D.J.

Respectfully submitted,

**GOODWIN PROCTER, LLP**

By 

Annemarie Hassett

P.A. I.D. # \_\_\_\_\_

599 Lexington Avenue

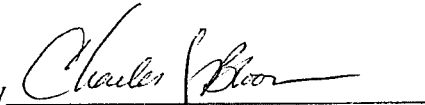
New York, NY 10022

(212) 813-8800

Dated: December 29, 2005

**ATTORNEYS FOR DEFENDANT  
IMPAX LABORATORIES, INC.**

**STEVENS & LEE, P.C.**

By 

Charles J. Bloom

620 Freedom Business Center

Suite 200

King of Prussia, PA 19406

(610) 205-6001

**ATTORNEYS FOR DEFENDANT,  
IMPAX LABORATORIES, INC.**

Dated: December 30, 2005

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

_____	)	
BIOVAIL LABORATORIES, INC.,	)	
a corporation of Barbados,	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 05-cv-1085
	)	
IMPAX LABORATORIES, INC.,	)	
a corporation of Delaware,	)	
Defendant.	)	
_____	)	

**DECLARATION AND AGREEMENT TO BE BOUND BY  
COURT ORDER GOVERNING CONFIDENTIALITY OF INFORMATION**

1. I, \_\_\_\_\_, have been asked by counsel for (Plaintiff/Defendant) in the above-captioned matter to review certain documents or other information which is confidential and subject to a Stipulated Confidentiality Agreement and Protective Order ("the Protective Order") entered by the court which governs the use of Confidential Information (as defined in the "Protective Order").

2. My present residential address is \_\_\_\_\_.

My present employer is \_\_\_\_\_ and

the address of my present employer is \_\_\_\_\_.

My present occupation or job description is \_\_\_\_\_.

3. Counsel for the (Plaintiff/Defendant) has explained to me that I am not permitted to disclose the Confidential Information or use documents containing Confidential Information for any purpose other than as permitted in the Protective Order.

**Exhibit A**

4. I have reviewed the Protective Order governing the use of this Confidential Information and agree to be bound thereby, and voluntarily submit to the jurisdiction of the United States District Court for the Eastern District of Pennsylvania with respect to the enforcement of said Protective Order, or with respect to any other order issued by the Court governing the use of Confidential Information.

Dated: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
**Title**

**Exhibit A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

\_\_\_\_\_  
BIOVAIL LABORATORIES, INC.,  
a corporation of Barbados,  
Plaintiff,

v.

\_\_\_\_\_  
IMPAX LABORATORIES, INC.,  
a corporation of Delaware,  
Defendant.  
\_\_\_\_\_

)  
)  
)  
)  
)  
) Civil Action No. 05-cv-1085  
)  
)  
)  
)  
)

**NOTICE OF ELECTION TO ADOPT**  
**STIPULATED ORDER ON CONFIDENTIALITY AGREEMENT**  
**AND PROTECTIVE ORDER**

1. \_\_\_\_\_, a  
non-party to the above-captioned litigation, has been requested and/or subpoenaed by a party to  
produce discovery containing Confidential Information in connection with the above-captioned  
litigation.

2. \_\_\_\_\_  
hereby elects to adopt the terms of the Stipulated Confidentiality Agreement and Protective  
Order dated January \_\_\_\_, 2005 (herein, the "Protective Order") with regard to its production of  
Confidential Information.

3. The provisions of the Protective Order shall apply to written discovery and  
testimony produced by \_\_\_\_\_ as if such discovery  
were being provided by a party. \_\_\_\_\_ shall have the same  
rights and obligations under the Protective Order as held by the parties.

**Exhibit B**



Dated: \_\_\_\_\_

By: \_\_\_\_\_

Title: \_\_\_\_\_

**Exhibit B**